

# EXHIBIT 7

Excerpt from Deposition of  
Terry Grinder

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND )  
COMPOUNDING PHARMACY, ) MDL No. 2419  
INC. PRODUCTS LIABILITY ) Master Docket No.:  
LITIGATION ) 1:13-md-2419-RWZ  
 )  
THIS DOCUMENT RELATES TO: ) Honorable Rya W. Zobel  
All Actions )  
 )

VIDEOTAPED DEPOSITION OF:

TERRY W. GRINDER, DPH

Taken on behalf of the Plaintiffs

September 14, 2015

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1 contaminated epidural steroid injections that were  
2 imported into Tennessee from a compounding pharmacy  
3 known as the New England Compounding Center?

4 MR. WELLS: Object to form.

5 BY MR. NOLAN:

6 Q. You can go ahead and answer.

7 A. I knew about the circumstances. I didn't know  
8 about the litigation --

9 Q. Okay.

10 A. -- until this was served.

11 Q. Well, when I ask you questions today, I'm going  
12 to be asking you about the pharmacy rules and laws as  
13 they existed in Tennessee in 2011 and in 2012, before  
14 the fungal meningitis outbreak.

15 Do you understand that?

16 A. Yes.

17 Q. Okay. With that in mind, could you tell us  
18 what a compounding pharmacy is.

19 A. Compounding is defined in state law as the  
20 prescribing and the preparation of a patient-specific  
21 drug product.

22 Q. Okay. And so what is the difference between a  
23 compounding pharmacy and a licensed pharmaceutical  
24 manufacturer?

25 A. Manufacturers, of course, would be under FDA

1 jurisdiction, and they would be manufacturing bulk  
2 products; whereas a compounding pharmacy typically would  
3 be compounding a patient-specific product based on a  
4 patient -- a prescriber-patient-pharmacy triad.

5 Q. Okay. And is it fair to understand that --  
6 that licensed pharmaceutical manufacturers that receive  
7 the FDA oversight receive a different degree of  
8 oversight than do compounding pharmacies?

9 MR. TARDIO: Object to the form.

10 BY MR. NOLAN:

11 Q. You can go ahead and answer.

12 (Clarification by the reporter.)

13 MR. NOLAN: Mr. Tardio.

14 BY MR. NOLAN:

15 Q. You can go ahead and answer.

16 A. Yes, manufacturers would be under a different  
17 scrutiny than -- than a pharmacy.

18 Q. Okay. So are drugs that are produced by  
19 licensed manufacturers, such as Pfizer, for example, FDA  
20 approved?

21 A. Yes. If the -- if they're FDA inspected and  
22 approved, then those drugs would be approved.

23 Q. All right. And how is that different from  
24 drugs that are made by compounding pharmacies pursuant  
25 to a patient-specific prescription?

1 A. They would not be under FDA scrutiny if they  
2 were properly compounded by a pharmacy.

3 Q. And do you know whether the FDA approval  
4 process for a company such as Pfizer involves patient  
5 safety?

6 MR. WELLS: Object to form.

7 THE WITNESS: I'm not sure I understand  
8 that one.

9 BY MR. NOLAN:

10 Q. Well, let me ask you this: Before the fungal  
11 meningitis catastrophe, specifically, what did the law  
12 require in terms of how compounding pharmacies were  
13 permitted to make and distribute medications in  
14 Tennessee?

15 MR. TARDIO: Object to the form.

16 THE WITNESS: Okay. Compounding was  
17 defined, and it involved the triad, as we mentioned  
18 before, of prescriber-patient-pharmacy. Typically, it  
19 was a patient-specific order that would have not been  
20 commercially available, and that also allowed for  
21 anticipatory compounding, based on prescribing habits of  
22 that prescriber.

23 BY MR. NOLAN:

24 Q. Okay. And -- and this triad of prescriber,  
25 patient, and pharmacy, is that arrangement set up for

1 the purpose of protecting patient safety?

2 A. Yes.

3 Q. And how does it promote patient safety?

4 A. It would allow a pharmacy to compound a  
5 specific product for a patient that might not be able to  
6 use the next nearest commercially available product, and  
7 it would allow the oversight of the Board of Pharmacy in  
8 that process.

9 Q. Okay. And so where is this -- this law about  
10 the circumstances under which compounding is legal?  
11 Where is it found?

12 A. Compounding is defined, I believe, in T.C.A.  
13 63-10. And I don't have a copy with me, but I believe  
14 it would be under "Definitions" in that section.

15 Q. Let me hand you a document that we're going to  
16 make Exhibit No. 573. And for the record, this is  
17 T.C.A. 63-10-204.

18 (Exhibit No. 573 was marked.)

19 BY MR. NOLAN:

20 Q. And let me first ask you whether this is the  
21 law that you were mentioning a moment ago.

22 A. Yes, it is.

23 Q. Okay. And so this law defines when  
24 it's appropriate to engage in compounding; is that  
25 correct?

1 MR. TARDIO: Object to the form.

2 BY MR. NOLAN:

3 Q. You can go ahead and answer.

4 MS. PUIG: Counsel, this is Yvonne. May I  
5 interrupt only briefly? Is he looking at one in force  
6 and effect in 2012 or currently?

7 MR. NOLAN: He's looking at the one that  
8 was in force in 2012 that became effective on August  
9 11th, 2010.

10 MS. PUIG: Very good. Thank you so much.  
11 I'm going to pull it up.

12 MR. NOLAN: Sure.

13 MS. PUIG: Thank you.

14 BY MR. NOLAN:

15 Q. So let me ask it this way: What does this law  
16 do?

17 A. It allows a pharmacy to provide a specific  
18 medication for patients that might not otherwise be able  
19 to use the next nearest commercially available product.

20 Q. Okay. And so how many circumstances does it  
21 list here in which it's appropriate to compound a  
22 medication?

23 A. (A), (B), and (C); it'd be three.

24 Q. Okay. And so let's talk about circumstance

25 (A). What is that circumstance when it's appropriate to

1 compound a drug?

2 A. That, again, is the triad as a result of the  
3 prescription order initiative based on the  
4 prescriber-patient-pharmacist relationship in the course  
5 of professional practice.

6 Q. Okay. Now, let's look at circumstance (B), and  
7 I'm going to read that into the record.

8 A. Okay.

9 Q. It says: "In anticipation of prescription  
10 orders based on routine, regularly observed prescribing  
11 patterns."

12 Have I read that correctly?

13 A. Yes.

14 Q. Okay. And is that the circumstance that you  
15 mentioned involving anticipatory compounding?

16 A. Yes.

17 Q. So am I correct in understanding that if a  
18 particular compounding pharmacy has a customer -- say,  
19 Dr. Smith, for example -- and they know that Dr. Smith  
20 writes ten patient-specific prescriptions for a  
21 particular medication each week, it's okay for that  
22 pharmacy to, on Monday morning, compound ten vials of  
23 that particular medicine anticipating that they will  
24 actually receive ten patient-specific orders as is  
25 Dr. Smith's custom?



1 MR. TARDIO: Object to the leading.

2 BY MR. NOLAN:

3 Q. You can go ahead and answer.

4 MR. WELLS: Object to form.

5 THE WITNESS: Yes.

6 BY MR. NOLAN:

7 Q. Okay. So that -- that type of "in anticipation  
8 of prescription" orders based upon routine, regularly  
9 observed prescribing patterns, does it allow for the  
10 making of compounded medications in bulk and sending  
11 them to some customer without ever receiving  
12 patient-specific prescriptions?

13 A. That was not the idea when the -- when this  
14 particular clause was put in, but I'm not an attorney.  
15 I can't --

16 Q. Okay. Well, since you've been there, or before  
17 the fungal men- -- meningitis outbreak, has this  
18 language, "In anticipation of prescription orders based  
19 on routine, regularly observed prescribing patterns,"  
20 always been in this particular law, to your knowledge?

21 MR. WELLS: Object to form.

22 THE WITNESS: For as long as I recall,  
23 yes.

24 BY MR. NOLAN:

25 Q. Okay. And then am I right that the third

1 circumstance listed here, does that involve research or  
2 testing or -- or analysis-type endeavors?

3 A. It does.

4 Q. Is that -- what is that, like clinical trials?  
5 Or what sort of circumstance does that come up in?

6 A. It could be the drug researches or teaching  
7 purposes or for chemical analysis, but it's not subject  
8 to sale or dispensing.

9 Q. And does the individual prescription rule, as  
10 found in this statute, allow for the making of -- of  
11 bulk medications by compounders for distribution without  
12 individual prescriptions?

13 MR. TARDIO: Object to the form.

14 MR. WELLS: Object to form.

15 MR. TARDIO: Asked and answered.

16 BY MR. NOLAN:

17 Q. You can go ahead.

18 A. Back to the triad analogy, if any of the three  
19 are missing, it would not be typical compounding.

20 Q. Could I give you a piece of paper, if I could,  
21 and ask you to just maybe draw for us kind of a  
22 conceptual representation of this triad that you're  
23 mentioning (tendering).

24 A. Sure (drawing).

25 MR. WELLS: Is that an extra copy, George?

1 MR. NOLAN: Of the statute?

2 MR. KRAUSE: Do you not have one? We've  
3 got one here.

4 MR. NOLAN: We've got one.

5 THE WITNESS: There is your (tendering)...

6 MR. WELLS: Thank you.

7 BY MR. NOLAN:

8 Q. Could you hold that up to the camera and just  
9 explain --

10 A. Sure.

11 Q. -- this to us, what this means.

12 A. As the patient sees the prescriber, proper  
13 treatment is determined, an order is sent to the  
14 pharmacy specific for that patient, and the pharmacy  
15 dispenses it to the patient.

16 Q. I see. Let me make that Exhibit No. 574.

17 (Exhibit No. 574 was marked.)

18 MS. HAMPTON: I'm sorry; may I see that?

19 MR. NOLAN: Yes, you can.

20 BY MR. NOLAN:

21 Q. Let me hand you a document that we're going to  
22 make 575.

23 (Exhibit No. 575 was marked.)

24 BY MR. NOLAN:

25 Q. And, sir, I'm going to represent to you that

1 this is a -- this is a document that has been produced  
2 in the context of this litigation to us, and it's  
3 labeled "Prescription Order Form" at the top. And you  
4 see NECC's logo there. And the date is July 24th of  
5 2012.

6 Now, as you look at this document, do you see  
7 that it appears to be placing an order for two drugs,  
8 one of which is called methylprednisolone? Do you see  
9 that?

10 A. Yes.

11 Q. Okay. And how many units of this drug are  
12 being requested apparently by this order form?

13 A. It says 500 units.

14 Q. Okay. And you see where there is a column for  
15 the names of patients?

16 A. Yes.

17 Q. And so how many patient names do you see listed  
18 on that column?

19 A. None.

20 Q. Okay. Does this order form comply with  
21 Tennessee law as far as you're concerned?

22 MR. TARDIO: Object to the form.

23 MR. WELLS: Object to form.

24 MR. TARDIO: Object to the undisclosed  
25 expert testimony and legal conclusions.

1 BY MR. NOLAN:

2 Q. You can go ahead and answer.

3 A. This wouldn't meet several of our requirements  
4 for a prescription order.

5 Q. Could you tell us what requirements that does  
6 not meet for a prescription order.

7 A. Number one would be the name of the patient.

8 Q. Okay.

9 A. Directions for use.

10 Q. Okay.

11 A. And that's -- that'd be the main thing to make  
12 it more compliant with a prescription order.

13 Q. Okay. Now, I'm going to represent to you that,  
14 in addition to using order forms like the one you have  
15 in front of you, one of the parties in this case, at the  
16 request of NECC, occasionally sent lists of patient  
17 names to NECC that did not necessarily correspond with  
18 who would receive the drug.

19 So they didn't send a list every time they used  
20 an order form like that. And the few times that they  
21 did send a list, the names on the list did not mean that  
22 the patients would actually receive that particular  
23 medication. Okay?

24 From a regulatory standpoint in Tennessee, does  
25 that arrangement comply with the pharmacy rules as you

1 understand them?

2 MR. TARDIO: Object to the form.

3 MR. WELLS: Object to form.

4 MR. TARDIO: Object to the opinion  
5 testimony and legal conclusions.

6 BY MR. NOLAN:

7 Q. You can go ahead and answer.

8 A. Can we clarify exactly what you're asking?

9 Q. Sure. What I'm saying is that at some point --  
10 I'm saying that one of the parties in this case, a  
11 party called Saint Thomas Outpatient Neurosurgical  
12 Center, began buying vials of what we call MPA,  
13 methylprednisolone acetate, using order forms like this  
14 that didn't have patient names on them.

15 A. Okay.

16 Q. And that at some point in time, one of the  
17 sales reps for NECC asked the facility to send lists of  
18 patients. And the facility explained, Well, we really  
19 can't do that. We have lists we can print out, but that  
20 doesn't necessarily correspond with who's going to  
21 receive these particular shots. And the sales rep said,  
22 That's okay; just send the list anyway.

23 And then the local facility, the Saint Thomas  
24 Outpatient Neurosurgical Center, sent some patient  
25 lists, even though they didn't necessarily match up with

1 who would receive MPA from that particular pharmacy.

2 Do you understand so far what I've explained?

3 A. Yes.

4 Q. Does that comply with the Tennessee rules and  
5 laws as you understand them?

6 MR. TARDIO: Same objections.

7 THE WITNESS: That would not meet the  
8 requirement for compounding.

9 BY MR. NOLAN:

10 Q. Do you know why in the world a compounding  
11 pharmacy would ask a customer to send a random list of  
12 patient names?

13 MR. TARDIO: Object to the form.

14 MR. WELLS: Object to form.

15 THE WITNESS: Any -- any answer I would  
16 have would only be speculation and...

17 BY MR. NOLAN:

18 Q. Okay. So if a -- if a company planned to sell  
19 medications in Tennessee in bulk without individual  
20 patient-specific prescriptions, what type of license  
21 would the company need?

22 A. A manufacturer's license.

23 Q. Okay. And so is that the type of license that  
24 would be required to sell FDA-approved drugs such as  
25 Depo-Medrol made by Pfizer, for example?

1 A. That would be either a manufacturer or a  
2 wholesaler license.

3 Q. Okay. And what type of license did NECC have?

4 A. A pharmacy license.

5 Q. All right. So was NECC authorized to sell  
6 medications in bulk in Tennessee without  
7 patient-specific prescriptions?

8 A. They were not properly licensed to do so.

9 Q. Now, has -- has your job ever included  
10 answering phone calls from healthcare providers who have  
11 questions about pharmacy laws?

12 A. Very much so.

13 Q. All right. And do you remember receiving a  
14 phone call from a pharmacist named Martin Kelvas, who  
15 was the Director of Pharmacy Services at Saint Thomas  
16 Hospital in early 2011?

17 A. I don't recall that specific call or, you know,  
18 any specific conversation.

19 Q. All right. So does that mean that no such call  
20 occurred, or does it mean maybe there was a call and you  
21 talk to a lot of people and you don't remember every  
22 single call that you --

23 A. We have lots of calls daily from lots of  
24 different people, and I just can't recall the specifics.

25 Q. All right. Well, I'll represent to you that



1 Dr. Kelvas has already given some testimony in this case  
2 and that during that testimony, he explained that in  
3 March of 2011, a New England Compounding Center sales  
4 representative came and met with him and solicited the  
5 hospital's business and tried to sell the hospital  
6 compounded medications.

7 And he didn't think that that arrangement was  
8 appropriate or legal, so he called the Tennessee Board  
9 of Pharmacy, and he talked with you. And according to  
10 him, you basically explained two things: First, that  
11 medications could only be procured from a compounding  
12 pharmacy pursuant to a patient-specific prescription  
13 involving the three-way relationship that you've  
14 explained.

15 A. Uh-huh.

16 Q. And secondly, that medications can only be  
17 purchased without prescriptions from someone with a  
18 manufacturer's license.

19 Is that -- is Mr. Kelvas's description in that  
20 regard consistent with what you would typically tell  
21 people back in the 2011 time frame?

22 MR. TARDIO: Object to the form.

23 MR. WELLS: Object to form.

24 BY MR. NOLAN:

25 Q. You can go ahead and answer.

1 A. Yes.

2 Q. Okay.

3 MS. PUIG: Mr. Nolan, could you repeat the  
4 question. At the middle of it, your voice trailed off.

5 MR. NOLAN: I think it would be best if we  
6 had the court reporter read back the question.

7 MS. PUIG: Very good. Thank you so much.

8 (Requested portion read.)

9 MR. NOLAN: And could you go ahead and  
10 read the answer.

11 COURT REPORTER: The answer was "yes."

12 BY MR. NOLAN:

13 Q. So when -- back in the 2011 time frame, if  
14 someone called with a question about buying medications  
15 from a compounding pharmacy, what would you typically  
16 tell them?

17 A. We would have told them that a compounding  
18 pharmacy could only dispense products that's prepared  
19 under the triad definition of compounding, and it had to  
20 be patient specific.

21 Q. And is that the explanation that you would give  
22 to anyone who would call with a question like that?

23 A. Yes, it is.

24 Q. Okay. So would that mean you would give the  
25 same answer, whether the person calling is a hospital

1 pharmacist or the manager or director of an ambulatory  
2 surgery center?

3 MR. TARDIO: Object to the form.

4 BY MR. NOLAN:

5 Q. You can go ahead and answer.

6 A. Yes.

7 Q. Let me hand you a -- a document that we've  
8 already made Exhibit No. 526 in this litigation. And,  
9 Dr. Grinder, I'm going to represent to you that this is  
10 a document that was produced to us by the Saint Thomas  
11 Outpatient Neurosurgical Center, and it consists of some  
12 of the written information that the New England  
13 Compounding Center provided to that particular clinic.  
14 Okay?

15 And if we look on the second page, you see  
16 paragraph G, which reads "Dispensing"?

17 A. Yes.

18 Q. Okay. And I want to read it into the record.  
19 It says, "Product is dispensed by patient-specific  
20 prescription only. There must be a specific  
21 practitioner-patient-pharmacist relationship to dispense  
22 to an individual patient or facility."

23 Have I read that correctly?

24 A. Yes.

25 Q. And is that statement consistent with or

1 similar to what you would tell people if they called  
2 your office with questions about how compounding  
3 pharmacies were supposed to work?

4 A. It would be.

5 Q. Now, I'd like to talk with you for a moment, if  
6 I could, about the rules that apply to the -- the  
7 labeling of compounded medications.

8 Are you generally familiar with those rules?

9 A. Yes.

10 Q. And could you tell us basically how compounded  
11 medications were supposed to be labeled if they were  
12 being distributed to patients in Tennessee.

13 A. A prescription label should include at least  
14 the patient's name, drug name and strength, and  
15 directions for use, as well as the date it was  
16 dispensed.

17 Q. And have you brought with you today a vial of  
18 methylprednisolone acetate that the Tennessee Board of  
19 Pharmacy procured during its inspection of the Saint  
20 Thomas Outpatient Neurosurgical Center?

21 A. Actually, it was procured, I think, by the  
22 Department of Health --

23 Q. Okay.

24 A. -- not the Board of Pharmacy. But, yes, I do  
25 have a vial.